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PO Box 19928
Alexandria, VA 22320

EXAMINER

SRIVASTAVA, KAILASH C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 09/15/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/049,552

Applicant(s)

MARTIN ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 18, 2002 as Paper Number 5.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' Preliminary Amendment filed 14 February 2002 as Paper Number 5 is acknowledged and entered.
2. Claims 16-35 are pending and are examined on merits.

Information Disclosure Statement

3. Applicants' Information Disclosure (i.e., IDS) filed February 14, 2002 as paper number 6 has been made of record and considered.

Priority

4. Applicants' claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 16-17 and 33-34 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims. The claims are directed to a cosmetic treatment method to combat skin aging, wherein a composition comprising a material obtained from culture of a member of family Pseudomonadaceae, mixed with pharmaceutical excipients is applied to skin or scalp.

From the record of the present written disclosure, the specification, while enabling for obtaining a cosmetic composition comprising mixtures of pharmaceutical excipients with material obtained from two Pseudomonad species (i.e., *Pseudomonas vesicularis* or *Pseudomonas maltophilia*) does not reasonably provide teaching to obtain said material from any, or all strains of *Pseudomonas* or all members of family Pseudomonadaceae (See Specification Page 7, Lines 19 to 39). Furthermore, the examples in the specification demonstrate cosmetic preparations to treat skin comprising lyophilizate from only two different *Pseudomonas* species (See for e.g., specification Page 8, Line 10 to Page 13, Line

11) mentioned above. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to extrapolate the claimed invention to either any and all *Pseudomonas* species/strains, or all members of family Pseudomonadaceae or to an extract of Pseudomonads. In any case, Pseudomonadaceae is sufficiently large family with a number of divergent members, and in the absence of demonstrated evidence of record that the said material (i.e., lyophilizate) crosses the spectrum of all/majority of members of family Pseudomonadaceae, the claimed invention is not considered enabled.

Furthermore, from the record of the present written disclosure, claims 16-17 and 33-34 are also non-enabling for the scope of the claims with regard to the bacterial extract. Applicants have not exemplified preparation of bacterial extract. They have merely demonstrated culturing *Pseudomonas vesicularis* or *Pseudomonas maltophilia* in a bacterial culture medium (i.e., Nutrient broth) and harvesting the biomass which is subsequently lyophilized (See, Example 1, Page 7, Lines 19 to 39) and in remaining of the examples incorporated either in a cosmetic composition or to evaluate the activities of elastase or hyaluronidase (See for e.g., specification Page 8, Line 10 to Page 13, Line 11). Thus, methods to prepare an extract of a bacterium belonging to family Pseudomonadaceae is clearly not supported in the specification.

An ordinary artisan would not be able to practice the invention from any or all members of family Pseudomonadaceae because in absence of a teaching about all the members of family Pseudomonadaceae and a method to prepare the bacterial extract, said method comprising details of each and every step and components/ingredients (e.g., solvents, temperature, pH, volumetric ratios for solvents and bacterial cultures etc.). Undue experimentation will be required to obtain a cosmetic composition comprising extract from any member of family Pseudomonadaceae due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 16-35 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 16-21 and 33-35 as written are very confusing, difficult to understand, and thus indefinite. Applicants are requested to clearly, concisely and succinctly rewrite the claims so that the claims clearly indicate the applicants' invention.
- Claim 16 is rejected as being indefinite because of the term "including". This term is similar to term "include" and is therefore, indefinite because it is not clear whether the term is open, like the conventional term "comprising" or whether the term excludes other ingredients, like the term "consisting of". It is suggested that the applicants use the transitional phrase -"comprises".
- The recitation, "derivative" in claims 16 and 33 renders those claims unclear as well as confusing, and therefore indefinite because the term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter.
- The phrase, "fraction obtained by chemical modification certain functional group of said biomass" in claims 16 and 33 renders those claims unclear as well as confusing, and therefore indefinite because the terms "fraction", "Chemical modification", "functional group" and "biomass" in said phrase are not clearly defined. For example, what is meant by the term "fraction"? A portion of bacterial cell or the culture medium or partially disintegrated cells or a chemical moiety obtained after separating the cells of the organisms from the culture medium in which the cells were cultivated? Similarly, what is the definition of a fraction? In the context of fraction, applicants need to define the steps (e.g., gel filtration, ion chromatography, electrophoresis or other separation techniques prevalent in the art to obtain said fraction. What does the term "biomass" encompass? The complete culture of said organism or just the cellular component of the organism or what portions of culture? i.e. the terms comprising the phrase "fraction obtained by chemical

modification certain functional group of said biomass" do not define the metes and bounds of the claimed subject matter.

- Term "extract" renders Claims 16-17, 20-21 and 33-34 vague and indefinite, because this term, in and of itself, does not adequately delineate its metes and bounds. For example, is the said extract obtained by extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the organism is said extract obtained? Since the extract itself is clearly essential to the claimed invention, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.
- The limitation "bacterial solids" is recited in Claims 17, 21 and 34. There is insufficient antecedent basis for this limitation in the cited claims, because Claim 16 from which Claims 17 and 21 depend and Claim 33 from which Claim 34 depends do not cite "bacterial solids".
- The phrase, ""bacterial solids" renders Claims 17, 21 and 34 vague and indefinite because this recitation is unclear as well as confusing, and therefore, indefinite. The phrase, "bacterial solids" does not clearly define the metes and bounds of the claimed subject matter. The examiner suggests that the applicants define the term, "bacterial solids".
- The phrase, "partially dehydrated" renders Claim 34 vague and indefinite because this recitation is unclear as well as confusing, and therefore, indefinite. The phrase, "partially dehydrated" does not clearly define the metes and bounds of the claimed subject matter. The examiner suggests that the applicants define the term, "partially dehydrated".

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections – 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16, 18, 21-22 and 33 are rejected under 35 U.S.C. §102(b) as anticipated by Bonfils et al. (US Patent 5,086,040) with evidence provided by Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page 1575).

Bonfils et al. teach a method to stimulate hair growth (Column 2, Lines 18-31 and Column 4, Lines 27-34) with application of a cosmetic or dermatological composition/cream to either scalp or hair of a warm blooded animal, including human, wherein said cosmetic or dermatological composition/cream comprises a glycoprotein extract of a Gram negative bacterium, i.e., *Pseudomonas aeruginosa* mixed with pharmaceutical excipients (e. g., hydrogenated lanoline). Since said glycoprotein extract is from *Pseudomonas aeruginosa* (Column 1, Lines 26-30), Bonfils et al. teach a cosmetic or dermatological composition/cream comprising a glycoprotein fraction obtained from at least one bacterium belonging to family Pseudomonadaceae. Also, said method inherently helps the skin to combat skin aging because it is applied to scalp, and, scalp is skin and subcutaneous tissue that normally bears hair (See Spraycar, M. (Editor), Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page 1575, Column 1, Lines 16-18). Furthermore, since the prior art reference teaches applying a composition comprising same ingredients as instantly claimed to the hair and skin, the prior art method inherently teaches inhibition of elastase or hyaluronidase activity (See e.g., In re Best, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

In this rejection under 35 U.S.C. §102(b), Spraycar (Editor, Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page 1575) is cited to merely support that scalp is skin and subcutaneous tissue that normally bears hair, and said reference is not cited as a prior art reference.

11. Claims 16, 18, 20, 21, 25, 27, 29, 31 and 33 are rejected under 35 U.S.C. §102(b) as anticipated by the English Abstract from Hamada et al. (JP 08208427).

Hamada et al. teach a method to moisturize, smoothen and provide luster to skin with application of a cream, wherein said cream comprises pharmaceutical excipients (e. g., dipropylene glycol) mixed with surfactants or moisturizers obtained from culturing *Pseudomonas sp.* Since said dermatological composition moisturizes, lustures and smoothen the skin, Hamada et al. teach skin preservation, improved skin appearance and

skin elasticity maintenance (JP 08208427, English Abstract, Lines 1-7). Furthermore, since the prior art reference teaches obtaining the same result through applying a composition comprising same ingredients as claimed in the instantly claimed invention, the prior art method inherently teaches inhibition of elastase or hyaluronidase activity.

Therefore, the reference deems to anticipate the cited claims.

12. Claims 16 and 18-35 are rejected under 35 U.S.C. §102(b) as anticipated by Spagnoli et al. (U.S. Patent 5,653,982).

Spagnoli et al. teach a method to treat/delay skin aging or skin regeneration by applying a cosmetic or dermatological preparation/ composition to human skin (Column 1, Lines 7-12; 44-46 and Column 6, Lines 26-32). Said preparation/ composition is in liquid/solid or cream form (Column 2, Lines 50-52, Example 2) and is comprised of pharmaceutical excipients/ carriers (Column 4, Lines 30-36, Example 2) and ribosome extracted from *Pseudomonas aeruginosa* (Column 2, Lines 24-30). Said ribosome is obtained as a fraction of biomass or a lysate from *Pseudomonas aeruginosa* by a process, wherein said *Pseudomonas aeruginosa*, a Gram negative bacterium is cultured on a liquid or a solid medium, subsequently cells of said bacterium are harvested and lysed to obtain a lysate of said bacterial culture, said lysate is concentrated and formulated into a dermatological/cosmetic formulation/ composition or cream (Column 2, Line 61 to Column 3, Line 67 and Column 12, Line 66 to Column 13, Line 2; Column 13, Line 15 to Column 14, Line 2 and Column 14, Lines 11-20). Since the prior art reference teaches a method to obtain the same result by topical administering of a composition comprising same ingredients as claimed in the instantly claimed invention, the prior art method inherently teaches inhibition of elastase or hyaluronidase activity (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Claim Rejections - 35 U.S.C. § 103

13. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

15. Claims 16-35 are rejected under 35 U.S.C. § 103 (a) as obvious over Bonfils et al. (US Patent 5,086,040) with evidence provided by Spraycar, M. (Editor), Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page1575) in view of English Abstract from Hamada et al. (JP 08208427) and Spagnoli et al. (U.S. Patent 5,653,982).

Teachings from Bonfils et al. (US Patent 5,086,040), Hamada et al. (JP 08208427) and Spagnoli et al (U.S. Patent 5,653,982) have already been discussed above.

Bonfils et al., however, do not explicitly teach moisturizing, lustrating and smoothening the skin because of administering their cosmetic or dermatological composition/cream to an individual. Hamada et al. teach skin preservation, improved skin appearance and skin elasticity maintenance (JP 08208427, English Abstract, Lines 1-7) by administering a cream comprising pharmaceutical excipients and surfactants or moisturizers obtained from culturing *Pseudomonas Sp.* Hamada et al., however, do not teach culturing said *Pseudomonas sp.*, or delineate how said surfactants or moisturizers were obtained from said *Pseudomonas sp.*

Spagnoli et al. beneficially teach method to culture a Gram negative bacterium, namely *Pseudomonas aeruginosa* and elaborate a process to obtain ribosomal fraction from the lysate of said culture of said *Pseudomonas aeruginosa* followed by a method to obtain cosmetic/dermatological composition or cream comprising said *Pseudomonas aeruginosa* ribosomal fraction (Column 2, Line 61 to Column 3, Line 67 and Column 12, Line 66 to Column 13, Line 2; Column 13, Line 15 to Column 14, Line 2 and Column 14, Lines 11-20).

An artisan of ordinary skill would be motivated to combine the teachings from each one of the cited references because each one of the cited prior art references teaches a method to treat/delay skin aging or skin regeneration, moisturize, smoothen and lustrate the skin with application of a dermatological/cosmetic preparation/composition or cream, wherein said dermatological/cosmetic preparation/composition or cream comprises pharmaceutical excipients (e. g., dipropylene glycol) mixed with surfactants or moisturizers or ribosomal fraction obtained from culturing *Pseudomonas sp.* Since said

dermatological/cosmetic composition or cream delays skin aging/ moisturizes, lustrates and smoothen the skin, the cited prior art references teach skin preservation, improved skin appearance and skin elasticity maintenance. While, Hamada et al. (JP 08208427, English Abstract, Lines 1-7) remedy the deficiency of clearly teaching skin preservation, improved skin appearance and skin elasticity maintenance in the teaching from Bonfils et al., Bonfils et al. teach a cosmetic or dermatological composition/cream comprising a fraction obtained from at least one bacterium belonging to family Pseudomonadaceae. Also, said method inherently helps the skin to combat skin aging because it is applied to scalp, and, scalp is skin and subcutaneous tissue that normally bears hair (Column 1, Lines 26-30; Column 2, Lines 18-31 and Column 4, Lines 26-34 and (See Spraycar, M. (Editor), Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page 1575, Column 1, Lines 16-18)). Spagnoli et al. remedy the deficiency in teachings of both Bonfils et al. and Hamada et al., because the latter prior art reference teaches methods to culture a Gram negative bacterium, namely *Pseudomonas aeruginosa* and elaborates a process to obtain ribosomal fraction from the lysate of said culture of said *Pseudomonas aeruginosa* followed by a method to obtain cosmetic/dermatological composition or cream comprising said *Pseudomonas aeruginosa* ribosomal fraction (Column 2, Line 61 to Column 3, Line 67 and Column 12, Line 66 to Column 13, Line 2; Column 13, Line 15 to Column 14, Line 2 and Column 14, Lines 11-20), wherein said cosmetic/dermatological composition or cream treats/delays skin aging or promotes skin regeneration by applying said cosmetic or dermatological preparation/ composition to human skin (Column 1, Lines 7-12; 44-46 and Column 6, Lines 26-32).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Bonfils et al. and Hamada et al. according to the teachings from Spagnoli et al. to distinctly delineate/incorporate the steps of culturing said Gram negative bacterium, namely *Pseudomonas aeruginosa*, preparing lysate from the culture of said Gram negative bacterium, preparing ribosomal fraction from said lysate and incorporating said ribosomal fraction into a dermatological/cosmetic composition/ cream in the method that Bonfils et al., and Hamada et al. teach, because Hamada et al. clarify Bonfils et al.'s teachings, teach a method to explicitly moisturize, smoothen and lustrate the skin with application of a cosmetic preparation/composition/ cream, wherein said cosmetic preparation/composition/ cream comprises pharmaceutical excipients (e. g., dipropylene glycol) mixed with surfactants or moisturizers obtained from culturing *Pseudomonas* sp. Since said dermatological composition moisturizes, lustrates and

smoothenes the skin, the cited prior art references teach skin preservation, improved skin appearance and skin elasticity maintenance. Thus, Hamada et al. remedy the deficiencies in the teachings from Bonfils et al., and Spagnoli et al. remedy deficiencies in the teachings from both Bonfils et al. and Hamada et al.

None of the above discussed prior art references teach the exact same weight percent of the component obtained from culturing *Pseudomonas* sp. However, adjustment of particular conventional working conditions (e.g., the quantities of each one of components in a given composition, or physical form (e.g., pomade cream, gel etc.) or method of application of a given composition) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.


Conclusion

16. No Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Daylight Saving, or Standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9306.


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August 28, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER